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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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05/01/2007

Gary Robinson

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07/14/2009

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/577,124		ROBINSON ET AL.	
	Examiner		Art Unit	
	GINNY PORTNER		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/26/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>notice to comply</u> . |

Art Unit: 1645

Election/Restrictions

Claims 1-39 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2-8, 30, 37-38 drawn to Method of regulating quorum sensing with an antibody that binds to the signaling molecule for a LuxR or homologue of LuxR (two species of antibody, one being anti-signaling molecule and one being an anti-idiotypic LuxR, pick one species to start with if this group is selected).

Group II, claim(s) 9-11, 15, drawn to antibodies that bind to LuxR or a homologue of LuxR
Or antibodies that represent the LuxR antigen and are anti-idiotypic antibodies (at least 3 species are recited in this group, pick one species to start with if this group is selected).

Group III, claim(s) 15-20, drawn to compositions that comprise one of: LuxR or LuxR homologue protein or fragment thereof or a LuxR or LuxR homologue or fragment thereof nucleic acid coding sequence or a quorum sensing signaling molecule composition (4 species of composition, pick one to start with if this group is selected).

Group IV, claim(s) 21,23-25 drawn to Methods of making a medicament that is a LuxR or LuxR homologue protein/polypeptide or nucleic acid or antibody or quorum signaling molecule (4 species of method, pick one to start with if this group is selected).

Group V, claim(s) 22, drawn to Methods of sensitizing an antibiotic resistant bacterium with a LuxR or LuxR homologue protein/polypeptide or nucleic acid or antibody or anti-idiotypic antibody for LuxR/LuxR homologue or quorum signaling molecule (5 species of method, pick one to start with if this group is selected).

Group VI, claim(s) 26-29 drawn to Methods of making a medicament that comprises an **antibiotic**, the antibiotic being specific for one of the recited species of pathogen set forth in claim 27 or species of disease set forth in claim 28).

Art Unit: 1645

Group VII, claim(s) 31-32 drawn to methods of detecting quorum sensing bacteria with antibodies that bind to LuxR or a homologue of LuxR Or antibodies that represent the LuxR antigen and are anti-idiotypic antibodies (at least 3 species of method are recited in this group, pick one species to start with if this group is selected).

Group VIII, claim(s) 33-34, drawn methods of detecting antibodies specific to LuxR or LuxR homologue protein (2 species of method, pick one to start with if this group is selected).

Group IX, claim(s) 35-36 and 39, drawn to kits that comprise an antibody or LuxR/LuxR homologue protein, or LuxR/LuxR homologue nucleic acid coding sequence or an antibiotic or a combination of any one or more of the above. (if this group is selected, then the desired kit combination should be pointed out and the claims that read on the selected combination).

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In light of the international search report that shows WO03/087145 describing the first appearing claimed special technical feature, the claimed inventions are not so linked by a special technical feature that makes a contribution over the prior art.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Please see each group listed above for the listed species and the claims that contain them.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

Art Unit: 1645

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Please see the listed groups above and the species encompassed by each group. Applicant is requested to identify the elected species and the claims that read on the elected species of invention for examination.

The following claim(s) are generic: Claim 1 is generic.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The chemical structure, biological function and effect of each of the claimed molecules differ from each other (ie. Proteins are made of amino acids and nucleic acid coding sequences are made up of a series of nucleotide sugar molecules that clearly differ in structure, function and biological effect from amino acids that make up proteins/polypeptides), and the first appearing invention directed to preventing activation of LuxR based upon antibody binding of a signaling molecule is disclosed in the prior art (see US PG-Pub 2003/009585, publication date May 22, 2003, [0169-0170]), therefore the first appearing invention/species does not make a contribution over the prior art, thus the claimed species are not so linked by a special technical feature that makes a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1645

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

1. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

This application contains sequence disclosures at pages 5, paragraph 3 and page 24, last line that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Claim 11 is objected to for not complying with the requirements of 37 CFR 1.821. The claims contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the fails to

Art Unit: 1645

comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below:

Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete. Applicants must correct the sequence submissions in the mentioned claims.

Examiner would like to point out that there is no information with regards to SEQ ID NO: of the amino acid sequences present in Figure 1, in the Brief Description of the Drawings for the mentioned Figure 1. If the Drawings contain amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) then the Brief Description of the Drawings needs to state the SEQ ID NO: for the nucleotide and/or amino acid sequences. Unless the appropriate SEQ ID NO: accompanies the nucleotide and/or amino acid sequences in the actual Drawing sheet.

General Observations/ Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Hyperlinks occur in the instant Specification at paragraphs [0011] and [0012]; they must be removed.

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.

The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
July 10, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645